

DEPARTMENT OF NEUROLOGICAL SURGERY

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Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

RE: Docket No. 97N-484S

Dear Sirs:

I would strongly urge against any further FDA regulatory action in the use of bone grafted material which we currently rely upon heavily in our practice to treat routine cervical disc disease and lower lumbar disc disease in cases where we have to decompress and fuse. Interference in the use of these materials would significantly impact our standard of care of treatment for such problems of instability of the cervical and lumbar spine, treatments which we have been using now for many, many years.

Please make sure that you understand the full potential implication of any such FDA regulation on the treatment of our patients.

Sincerely

Gerald M. Kadis, M.D.

GNK:shh

Community Care Clinics

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THE SOUTH GEORGIA NEUROLOGICAL INSTITUTE, P.C.

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